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Ti Fenestrated Plate SEP - 5 2003

510(k) SUMMARY

SUBMITTED BY

Wendy Spielberger
Lead, Regulatory and Clinical Affairs Staff
Interpore Cross International
181 Technology Drive
Irvine, California 92618
(949) 453-3200

June 6, 2003

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Appliance, Fixation, Spinal Interlaminal
Common/Usual Name:	Spinal Interlaminal Fixation
Product Classification:	Class II
Proprietary Name:	Ti Fenestrated Plate

PREDICATE DEVICE

Predicate device information is provided in this premarket notification.

INDICATIONS-FOR-USE

The Ti Fenestrated Plate is intended to be used as a temporary construct that assists normal healing and is not intended to replace normal body structures. The Ti Fenestrated Plate is intended to stabilize the spinal operative site during fusion procedures and should be removed after fusion.

The Ti Fenestrated Plate is attached to the spine posteriorly by means of Songer Cables. The levels of attachment are T1 to L5.

The Ti Fenestrated Plate is indicated for the following:

1. Degenerative Disc Disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Idiopathic scoliosis.
3. Kyphotic deformities of the spine.
4. Lordotic deformities of the spine.
5. Vertebral fracture or dislocation.
6. Tumors.
7. Spondylolisthesis.
8. Stenosis.
9. Pseudarthrosis.
10. Unsuccessful previous attempts at spinal fusion.

DEVICE DESCRIPTION

The Interpore Cross International Ti Fenestrated Plate is a titanium plate containing multiple holes along the length of the plate. The Ti Fenestrated Plate is intended for use in the thoracolumbar spine from T1-L5. The plate is secured to the posterior spine via Songer Cables. The Songer Cables are

placed through the holes in the Ti Fenestrated Plate and passed under and around the lamina. The plate and cable(s) are then secured to the spine using a tensioner/crimper instrument to obtain the appropriate tension level and to secure the cable crimp.

COMPARISON TO THE PREDICATE DEVICE

Based on the same indications for use, intended use, similarity in materials of construction and equivalent biomechanical performance, the Ti Fenestrated Plate is considered substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2003

Ms. Wendy Spielberger, RAC
Lead, Regulatory and Clinical Affairs Staff
Interpore Cross International
181 Technology Drive
Irvine, California 92618

Re: K031772
Trade Name: Ti Fenestrated Plate
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: June 6, 2003
Received: June 10, 2003

Dear Ms. Spielberger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031772

Device Name: **Ti Fenestrated Plate**

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter Use**
(PER 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031772

(Optional Format 1-2-96)